IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados, Plaintiff, v. ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION, Defendants.	C.A. No. 05-586 (KAJ)

ANDRX'S REPLY TO BIOVAIL'S OPPOSITION TO CONSOLIDATING BIOVAIL'S TWO SEPARATE ACTIONS ALLEGING INFRINGEMENT OF THE SAME PATENT AGAINST THE SAME ANDRX DEFENDANT

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I. Introduction

By first precipitating this motion, and then by attempting to inject an alleged discovery dispute into the briefing, Biovail squarely presents the question of whether it can use procedural shenanigans to re-litigate this Court's rulings. At the scheduling conference, this Court set a trial date sooner than Biovail had wanted (and later than Andrx had wanted). (Docket nos. 18, 20) Biovail has engaged in improper conduct in an attempt to vacate it. Specifically, Biovail filed a separate action instead of amending the complaint in this case, because, no matter what the Court ruled at the scheduling conference, it planned to argue for further delay. That is why, from the beginning, Biovail has refused to consolidate the two cases unless Andrx agreed to release the Court's trial date. Further, instead of even attempting to justify that maneuver in its opposition brief, Biovail has created an alleged discovery dispute in the first filed case in order to argue that the discovery dispute makes it necessary for the Court to vacate its ruling on the trial date in the event of consolidation.

Thus, Biovail calls upon the Court to make clear whether the litigants in this case should accept and proceed expeditiously upon the Court's rulings (be they favorable or unfavorable), or, in the alternative, take the Court's rulings as a challenge to be overcome by procedural machinations and sharp practice. We think the answer is clear.

Biovail essentially admits that its opposition to consolidation is all about delay. (*See* Opp. Memo. at 1.) It uses the entirety of its brief to plead for more time.[1] Yet, Biovail fails to

[1] Biovail's motivation to play for more time is clear under the Hatch Waxman Act, which automatically stays FDA approval of Andrx's would-be competitive drug for a period of 30 months or until there is a judgment in this case. Accordingly, every day that Biovail can delay this litigation amounts to more guaranteed monopoly sales and profits. Indeed, the economics of the market are such that it would even be profitable for Biovail to obtain delay even at the expense of substantial monetary sanctions imposed by the Court.

cite even a single case in which any court has modified an existing scheduling order in response to one party's amendment to include additional strengths in its ANDA. Its brief is devoid of legal authority for a reason: Biovail's position lacks support. By statute, this type of case is supposed to be resolved in an expedited manner. 21 U.S.C. § 355(j)(5)(B)(iii). Biovail's approach has been to stall on the consolidation issue until Andrx acted, and then to argue that Biovail would be inconvenienced by consolidation unless given more time. Andrx acted promptly in moving for consolidation, and has already produced documents, answers and samples for all the strengths of the proposed generic product at issue in the later filed action – all in the course of discovery in the first filed case. There is no excuse for delay.

Civil action nos. 05-730 and 05-586 involve the same patent, same product (albeit at different strengths) and same FDA application. The same claim language is at issue. These cases should be consolidated under this Court's current scheduling order.

II. Summary Of Argument

a. None of Biovail's arguments against consolidation under the current scheduling order warrant delaying the consolidation and swift resolution of civil action nos. 05-586 and 05-730.

Biovail's focus on an alleged discovery issue arising out of the first filed case is obvious misdirection. If Biovail truly believed that it was in the right in its trumped-up dispute, it could have timely raised the issue with this Court in a discovery conference. Instead, it chose to avoid the Court's process for rapid resolution of bona fide discovery disputes. Without availing itself of the procedure that every other party before this Court must engage,[2] Biovail now seeks to leverage its alleged discovery dispute in the first filed case into a motion for reconsideration of

[2] Indeed, Andrx has had to schedule a discovery dispute conference with this Court due to Biovail's intransigence in discovery.

the trial schedule, and then to conflate its alleged discovery issues with consolidation. At the scheduling conference Biovail asked for a longer schedule, Andrx requested a shorter schedule and the Court made its determination. The Court's Order should stand.

Biovail's lamentation about the volume of Andrx's production in the first filed case amounts to rhetoric. Biovail seeks delay on the ground that there are too many documents for a major drug company and its large New York law firm to review. No doubt, if Andrx had produced fewer documents, Biovail would have sought delay on the ground that it needed to engage in motion practice. Biovail fails to disclose to the Court that it had been requesting documents related to all of Andrx's proposed product strengths since the beginning of discovery in the first filed suit – prior to the Court's scheduling conference. Biovail anticipated the volume of materials that it would receive in that production. Its pattern of conduct further manifests its desire to re-litigate this Court's November 14th Order.

Finally, Biovail's argument that consolidation would bring "five additional products" into this case is a veneer it applies to obstruct this Court's view of what Biovail's opposition really is – its chance for a schedule re-hearing. Biovail's "additional product" argument contradicts its own website and drug labeling. Biovail knows that, taken together, both cases involve a single product in multiple strengths. Its attempt to accentuate the differences among the tablet strengths of Andrx's proposed product lacks substance and is no basis for further delay.

III. Argument

A. Biovail's alleged discovery dispute in the first filed action is not a legitimate reason to delay the case's resolution after consolidation.

Biovail is attempting to convert a discovery dispute in the first filed case into an excuse for changing the existing schedule in the event of consolidation. Biovail has had access to this Court's discovery resolution forum for months. If its alleged problems with Andrx really began

in August of last year (prior to the scheduling conference in the first filed action), Biovail could and should have formally approached this Court well before January 6th. (Opp. Memo. at 1.) Even now, Biovail is not asking this Court to intervene and resolve its alleged discovery issues; it is only asking the Court to prolong the lawsuit. If Biovail's allegations had merit or if the discovery dispute were indeed prejudicing its case, Biovail would have asked this Court to intervene a long time ago. Instead, it waited to bring its allegations to this Court in a different forum and for a different purpose.

Biovail has fabricated its discovery dispute by asking for materials that would be difficult, if not impossible, to produce. Andrx timely produced samples for all strengths of its proposed product and representative samples of raw material for all strengths of its proposed product (including its active release and extended release pellets). Moreover, Andrx timely produced its ANDA, which states the identity of its suppliers of the raw materials Andrx has used, and intends to use, to make all the strengths of its proposed product. Those raw materials are available on the open market. But no matter how many times or how adamantly Biovail asks, Andrx will never be able to produce certain requested materials. For example, Biovail keeps asking Andrx for the specific materials that Andrx has used to produce the different strengths of Andrx's proposed product. (Ratliff Exhs. 14, 17.) That material no longer exists because it has been consumed in the manufacturing process (i.e. the specific materials Andrx used to produce its tablet samples are now in those samples). Furthermore, it would be extremely difficult, if not impossible, for Andrx to trace the sources of the raw material it used to produce each individual lot back to their original batches. Andrx has taken what it believes is a reasonable position – it has produced representative samples.

Biovail's argument for a trial extension based on 420 mg tablet dispute constitutes bad faith. By December 30, 2005 inclusive, Andrx had produced samples of every one of its finished products in every strength, representative samples of its intermediates (active and extended release pellets) and raw materials. The dispute regarding the 420 mg samples stems from the fact that, though Andrx produced those samples long ago, Biovail had alleged the samples were damaged. Andrx agreed to re-produce the 420 mg samples when Biovail returned the first produced sample. (*See e.g.,* Declaration of Matthew C. Marlowe ("Marlowe Decl."), Exh. E.) On the day that it filed its opposition brief, Biovail elected to return Andrx's earlier produced 420 mg samples and removed the impediment to Andrx's production of replacement samples. (Ratliff Exh. 17.) If Biovail had not returned the allegedly damaged samples, its litigation stance would have been untenable. Biovail's timing deprived Andrx of its ability to respond in accordance with its earlier letter. Biovail artificially created its primary argument for an extension.

B. Biovail's argument that the Court should postpone trial due to the volume of production amounts to re-litigation, and, if granted, would penalize Andrx for properly responding to Biovail's discovery requests.

Biovail's request for more time in light of the volume of documents produced is a feint. (*See* Opp. Memo. at 2.) Biovail asserts that "it must review and analyze over 100,000 documents…to determine the relative similarities and differences for each product."[3] (Opp. Memo. at 6.) Yet, Biovail does not to disclose to this Court that it has sought materials related to every strength of Andrx's proposed generic product at least since filing its first official discovery

[3] Andrx notes that Biovail has so far refused to produce documents responsive to almost all of its requests. Biovail also has not fulfilled its responsibility to answer interrogatories or make initial disclosures. By complaining that it has received too many documents from Andrx and simultaneous withholding Biovail's production of documents to Andrx, Biovail is doing its best to slow this case down and disadvantage Andrx.

request in the first filed case. (Marlowe Decl., Exh. F.) Biovail served Andrx with that request on November 4, 2005, prior to this Court's November 10th scheduling conference. (*See id.*) Thus, Biovail has long anticipated that it would receive the materials on which it now relies to argue for an extension. Neither it, nor its attorneys, are new to patent litigation. Biovail had the opportunity to make its case before the Court and the Court has spoken.

C. Biovail's remaining arguments are word games designed to lead this Court to the erroneous conclusion that the different strengths of Andrx's proposed product are so different that Biovail deserves more time to litigate.

In its effort to accentuate differences among the different strengths of Andrx's proposed product, Biovail contradicts its own publicly-held view that different strengths of the same product comprise one single product. Biovail repeatedly argues that consolidating civil action nos. 05-586 and 05-730 will introduce "five additional products" into the controversy and complicate an already "complex litigation." (*See e.g.* Opp. Memo. at i, 1, 2, 6, 7.) On that basis it claims to need more time.

Biovail knows that civil action nos. 05-586 and 05-730 taken together involve one product in different strengths as evidenced by the fact that ***its own website and labeling regard different strengths of the same product as one product.*** (Marlowe Decl., Exh. G.) Biovail's own website identifies Cardizem LA, the brand name version of Andrx's proposed generic drug, as a single product that comes in multiple strengths. That is, for the purpose of running its business, Biovail tells the world that Cardizem LA is a single product that comes in varying strengths. For the purpose of delaying this case, however, Biovail tells this Court that Andrx's generic corresponding product in varying strengths is actually many different products. In other words, Biovail tells the world one thing and tells this Court precisely the opposite.

Biovail's statement that, "Andrx, in fact, has not represented (nor can it) that the five additional products [sic] are identical in every way to the 420 mg Cardizem LA product," is similarly misleading. Again, Biovail's intent is to convince this Court that different strengths of Andrx's product must be very different – so different that Biovail and its putative experts need more time for this litigation. Certainly, Andrx can not say that the different strengths of its product are identical in every way – tablets of *different strengths* include *different amounts of the same active ingredient*. Andrx has stated that, from the perspective of the patent-at-issue in this case, the differences among the strengths of Andrx's proposed product are trivial because all of Andrx's proposed tablet strengths will contain a clinically effective amount of active ingredient.

IV. Conclusion

Throughout this proceeding, Biovail will clamor for more time. Biovail knows that its delay will keep Andrx's non-infringing product off the market – much as it happened the last time Biovail asserted the patent-in-suit against a different Andrx generic product. *Biovail Corp. Intern. v. Andrx Pharmaceuticals, Inc.*, 158 F.Supp.2d 1318 (S.D. Fla. 2000), *aff'd* 239 F.3d 1297 (Fed. Cir. 2001). Congress established a duty to expedite this type of case because of the strong financial incentive that brand name companies have in prolonging this type of lawsuit. Therefore, Andrx respectfully requests this Court to grant its motion for consolidation under the schedule ordered in civil action no. 05-586.

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